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HEART STIMULATOR

Technical Field

The present invention relates to a heart stimulator according to the preamble of claim 1.

Background Art

For certain conditions such as hypertrophic obstructive cardiomyopathy (HOCM) the patient's condition may improve if he or she is paced to 100% in the ventricle. In a state of HOCM the left ventricular wall is asymmetrically thickened. The interventricular septum thickness significantly exceeds that of the opposing posterolateral wall. A pressure gradient exists across the left ventricular outflow tract and during ventricular contraction, a progressive degree of outflow tract obstruction results. The conventional site of ventricular pacing is within the right ventricular apex and pacing, prior to intrinsic R-wave excitation, from this site can favourably alter the degree of obstruction. This has been clinically verified.

100% pacing in the ventricle requires understanding of a phenomenon referred to as fusion. Fusion means that the natural conduction time, which is the time interval between an atrial activity (a sensed P-wave or a delivered A-pulse) and the subsequent natural ventricular activity (R-wave), is the same as the time (AV-interval) between an atrial activity (again, a sensed P-wave or a delivered A-pulse) and the delivery of a ventricular stimulation pulse (V-pulse). Fusion is thus a condition where the V-pulse is delivered at the same time as the R-wave occurs. Thus, fusion means that the V-pulse occurs when the heart tissue is not capable of responding, i.e. it is refractory, a tissue refractory period starting at the depolarization event (R-wave) and remaining until repolarization (T-wave) occurs. Although not necessarily harmful to the heart, fusion causes loss of energy in the V-pulse, and should therefore be avoided to save pacemaker battery energy. For the purposes of this application, both the time interval between a P-wave or an A-

pulse, and a V-pulse will be referred to as the AV-interval.

To obtain 100% pacing beats with no fusion very short AV delays have been used. Such very short AV intervals are, however, non-physiologic and therefore it is highly desirable to prolong the AV interval while maintaining a continuous monitoring of fusion, such that the AV interval would be shortened automatically if fusion beats appear. Several attempts have been made to solve this problem.

Thus, US-A-5,534,016 and 5,713,930 describe techniques for optimizing the AV interval for therapeutic purposes for patients having HOCM. In the system according to US-A-5,534,016 the T-wave detection is monitored to detect when the AV interval is lengthened to the point of evoking a fusion beat, and in the system disclosed in US-A-5,713,930 the relationship between AV intervals and QT intervals (= the time interval between a delivered ventricular stimulus and resulting T-wave) is monitored and therefrom it is determined when AV intervals correspond to full capture and when AV intervals correspond to fusion.

Further, in US-A-5,507,782 a dual chamber pacemaker is described in which the longest AV interval providing for complete ventricular capture is determined from the wave form of the ventricular depolarization R-wave following a ventricular pacing pulse for the purpose of treating patients suffering from HOCM. In this document the problems related to fusion beats and the transition region between complete pacing and fusion are not at all dealt with.

Another way of solving the problem of fusion and providing a 100% pacing of the ventricle is by AV node ablation. AV node ablation is, however, an intervention associated with extra costs and the conduction pathway from the atria to the ventricles is then destroyed for all time so the patient will be completely depending on a pacemaker in the future with higher clinical risks in the event of a pacemaker failure.

The purpose of the present invention is to provide a new heart stimulator suitable for treating HOCM patients by

accomplishing 100% paced ventricular capture, which stimulator comprises a new type of evoked response detector suitable for detecting incipient fusion in a simple and reliable way.

Summary of the invention

This purpose is obtained by a heart stimulator of the type defined in the introductory portion of this description having the characterizing features of claim 1.

In the following the expression "sensed atrial signals" denotes sensed spontaneous atrial events (P-waves) as well as stimulated atrial events (A-pulses). The interval between a sensed spontaneous atrial event and the ventricular V-pulse is denoted by PV interval, and the interval between a stimulated atrial event and the ventricular V-pulse is denoted by AV interval. The PV interval is generally shorter than the AV interval. As noted above, however, for the purpose of this patent application the PV-interval as well as the AV-interval will be referred to as the AV-interval hereinafter.

Thus, in the stimulator according to the present invention the AV-interval is continuously monitored and automatically shortened if incipient fusion is detected. Thus an incipient fusion is detected by an evoked response detector from measured ventricular signals picked up by an ventricular electrode and containing the evoked response signal, and the used AV-interval will be adjusted accordingly to be as long as possible while avoiding the occurrence of fusion beats. From a haemodynamic point of view, e.g. ventricular filling and cardiac output, such a stimulator operation will give optimum results. Thus the stimulator according to the invention will operate with an AV-interval that is optimized with respect to haemodynamic conditions.

According to an advantageous embodiment of the heart stimulator according to the invention, the controlling means are adapted to modulate the AV-interval with a predetermined amount, and said comparison means is adapted to then compare the variation of said average amplitude values obtained

during said time window with a predetermined limit. A large variability is then a clear indication of incipient fusion.

According to another advantageous embodiment, said controlling means are adapted to regularly prolong the AV-interval with a predetermined amount and said comparison means is adapted to then compare said average amplitude values obtained during said time window of cardiac cycles with said predetermined limit value and/or compare the variation of said average amplitude values obtained during said time window with a predetermined limit. In this way, incipient fusion can be detected at a very early stage and by utilizing both an amplitude criterion and a variability criterion improved reliability is obtained.

According to still another advantageous embodiment of the heart stimulator according to the invention the evoked response detector is adapted to determine the DC level of the measured ventricular signal and subtract this DC level from each sample before the average value is formed. It is important to subtract the DC level from the measured signal picked up by the electrode to get a corrected signal for subsequent analysis.

According to yet another advantageous embodiment of the heart stimulator according to the invention a respiration signal determining means is provided for determining a respiration signal representing the respiration rate of the patient, from a predetermined number of said average values.

Brief Description of the Drawings

To explain the invention more in detail, selected embodiments of the heart stimulator according to the invention will now be described with reference to the drawings, on which figure 1 is a block diagram of the principal layout of the heart stimulator according to the invention,
figure 2 is a block diagram of the evoked response detector of the heart stimulator according to the invention,
figure 3 is a flow diagram illustrating the function of the embodiment of figures 1 and 2, and

figure 4 is a block diagram of the principal layout of a second embodiment of the heart stimulator according to the invention.

Description of Preferred Embodiments

It is previously known to distinguish between completely stimulated captures, fusion beats and losses of capture from analysis of average amplitude values of recorded ventricular signals during a predetermined time window after a pacemaker stimulation, see Åsa Uhrenius et al., "Evaluation of new Algorithms for Autocapture with Unipolar Leads", CARDIOSTIM 98, Nice, June 1998.

Figure 1 shows a block diagram of the principal layout of the heart stimulator according to the invention. The stimulator comprises a pulse generator 2 which through leads 5,6 and associated atrial and ventricular electrodes 7,9 are connected to the heart 8 of a patient. The pulse generator 2 is devised to produce stimulation pulses of varying amplitudes which through the leads 5,6 with their electrodes 7,9 are transferred to the heart 8. An evoked response detector 4 of the above mentioned type is connected to the ventricular lead 5. An atrial detector comprising atrial filtering and measuring means 17 is connected to the lead 6 for measuring amplitudes of signals picked up by the atrial electrode 9. Determining means 13 are connected to the evoked response detector 4 and to said atrial filtering and measuring means 17 for determining an incipient fusion AV-interval, i.e. the AV-interval at which incipient fusion was detected, from said measured atrial signals and detected incipient fusion beats. Controlling means 15 are connected to the determining means 13 and to the pulse generator 2 for controlling the pulse generator 2 to deliver stimulation pulses at a controlled AV interval which is shorter than said incipient fusion AV-interval.

The atrial filter and measurement means 17 and the evoked response detector 4 are disconnected by switches 19 and 11 from their respective leads 5,6 during stimulation.

The evoked response detector 4 comprises filter and measuring means 10. The filtered ventricular signals picked up by the ventricular electrode 7 are supplied to a storage means 21, an averaging means 16 and to comparison means 12 for detecting incipient fusion by comparing the average amplitude obtained during a predetermined time window of the cardiac cycle from the averaging means 16 with suitably selected limit values. As appears from the above mentioned publication by Åsa Uhrenius et al. completely stimulated captures result in a comparatively large constant average amplitude whereas an incipient fusion results in a decrease of the absolute value of this average amplitude.

As an alternative, the averaging means can be adapted to form a running average value of the measured ventricular signals during said predetermined time window from a predetermined number of the latest cardiac cycles and the comparison means can be adapted to receive said running average value and compare the average value obtained during said time window of each cardiac cycle with said running average value from immediately preceding cardiac cycles.

The above mentioned limit values of the comparison means 12 can be selected such that e.g. a 10% decrease of the measured average amplitude compared to the average amplitude in a situation of completely stimulated capture is indicated as an incipient fusion. Thus, a decrease of the absolute value of the average amplitude from e.g. 26mV to e.g. 23,5mV can be interpreted as incipient fusion. In this case, a running average value as described above of e.g. the ten last cardiac cycles, is suitably used as limit value in the comparison means 12 for obtaining an acceptable signal-to-noise ratio.

Timing means 14 are provided for determining said evoked response time window during which the ventricular signal is measured and stored. This evoked response window normally extends from 15 to 55 msec after stimulation.

Thus, after a blanking time of about 15 msec the measured evoked ventricular signal is sampled and digitized

during this evoked response time window and the average value of these samples is formed. This procedure is performed in the averaging means 16, which thus supplies to the comparison means 12 an average amplitude value obtained during said time window for each heart beat. A suitable sampling frequency can be e.g. 512 Hz, which results in about 20 samples per beat.

As also appears from the publication by Åsa Uhrenius et al., the variation in the average amplitude from different cardiac cycles is comparatively small in a situation of completely stimulated capture, whereas this variation increases in a fusion situation. Thus, as an alternative embodiment, the comparison means 12 can be adapted to compare the variability of average amplitude values obtained from different cardiac cycles with a predetermined variability limit to detect an incipient fusion.

The variability criterion for indicating incipient fusion should normally be more strict than the above discussed amplitude criterion. Thus, a variability increase in the average amplitude values of e.g. 25% compared to the variability at completely stimulated capture can be used as variability criterion in the comparison means 12 for indicating incipient fusion. An increase of the peak to peak variability in the average amplitude values from different cardiac cycles from e.g. 2,5mV to e.g. 3,0mV can be interpreted as incipient fusion. Also is this case a running average value from e.g. the ten latest cardiac cycles should preferably be used.

As a further improvement of this embodiment, the controlling means 15 can be adapted to carefully modulate the AV-interval with e.g. ±5 msec or ±10 msec. A large variability appearing in the average amplitudes is then a reliable indication of fusion.

As still another alternative, the controlling means 15 can be adapted to prolong at regular intervals the AV-interval with a predetermined amount, e.g. 10 msec, and the average amplitude or variability criteria described above are checked. If the average amplitude or variability criteria

then, for this prolonged AV-interval, indicate fusion or incipient fusion, the AV-interval is shortened by 20 msec. If no changes in average amplitude or variability are noted, the AV-interval is the correct one. This would mean that the heart stimulator chooses an AV-interval which is approximately 20 msec shorter than the AV-interval at which incipient fusion is detected. In this way, a kind of check is performed to determine if the heart stimulator operates close to fusion, and in this way incipient fusion can be detected at a very early stage.

In the heart stimulator acocording to the invention it is also possible to utilize both above described amplitude and variability criteria for determining an incipient fusion which normally further improves the detection reliability.

To obtain a reliable result it is also desirable to eliminate any DC level in the measured ventricular signal. This can be performed by sampling the measured ventricular signal before the emission of a stimulation pulse and forming an average value of these samples during a cardiac cycle. This average value represents the DC level and is subtracted from each sample of the subsequent measured ventricular signal.

Figure 2 shows in greater detail one embodiment of the evoked response detector of the heart stimulator according to the invention. The ventricular signal picked up by the lead 5 with its electrode 7 in figure 1 is supplied to a highpass filter 20. An amplifier 22 and an A/D converter 24 are provided for amplifying and A/D converting respectively the filtered signal. The block 26 comprises a digital signal processor for calculating the average amplitudes of the measured ventricular signals and comparing them with suitably selected limit values as described above for detecting an incipient fusion.

Figure 3 is a flow diagram illustrating the function of the embodiment illustrated in figures 1 and 2 of the heart stimulator according to the invention for securing a 100% paced ventricular capture while optimizing the AV-interval

with respect to haemodynamic conditions. At block 40 an AV interval is selected which is optimal with respect to the ventricular filling of the patient in question. This AV interval is programmed by a doctor. The pulse generator 2 starts the HOCM therapy mode with a short AV-interval, block 42.

The evoked response signal average amplitude during each heart beat is monitored by the evoked response detector 4, and the AV interval is prolonged if it is shorter than the programmed AV interval, block 44.

It is checked that the evoked response average amplitude has a sufficiently high, substantially constant absolute value, at block 46. If yes, the AV interval is prolonged while monitoring the evoked response amplitude according to the step of block 44. If no, the AV interval is shortened with e.g. 5 msec while monitoring the evoked response amplitude, at block 48.

It is then checked whether the average value formed from sampled values of the evoked response signal as described above maintains a sufficiently high and constant absolute value according to the predetermined requirements, at block 50. If yes, the procedure reverts to block 44, viz. the AV interval is once again prolonged, provided that it is shorter than the programmed AV interval, while monitoring the evoked response amplitude, and the procedure is continued to block 46 as described above. If no, the procedure reverts to block 48, viz. the AV interval is further shortened with 5 msec while monitoring the evoked response amplitude.

Thus the heart stimulator according to the invention is operating at an AV-interval which is as close as possible to the optimal AV-interval programmed by a doctor while securing all the time that occurrence of fusion is avoided. Thus, in this way a continuous suboptimization is obtained of the programmed optimal AV-interval set by the doctor. If the evoked response average amplitude does not satisfy predetermined criteria with respect to the absolute averaged value of the amplitude and possibly the variability of the

amplitude, the AV interval is automatically shortened till these criteria are again satisfied.

Figure 4 is a block diagram of the principal layout of a second embodiment of the heart stimulator according to the invention.

This embodiment comprises, in addition to the elements of the embodiment shown in figure 1, a respiration signal determining means 28, which is supplied with the average signal values generated by the averaging means 16. The respiration signal determining means 28 generates a respiration signal, representing the respiration rate of the patient, from a predetermined number of evoked response average values. The respiration signal is supplied to the AV-interval determining means for use in the control of the pulse generator 2. The use of the respiration rate to control the operation of a pacemaker, is well known to the person skilled in the art, cf. e.g. US-A-4,702,253, and is therefore not described herein.

Claims

1. A heart stimulator comprising atrial and ventricular stimulating means (2) for producing stimulation pulses for delivery to a patient's heart (8), atrial sensing means (6,9,17) for sensing atrial signals, an evoked response detector (4) for detecting evoked response signals, determining means (13) for determining an incipient fusion AV-interval from said sensed atrial signals and detected evoked response signals, and controlling means (15) for controlling said ventricular stimulating means to deliver stimulation pulses at a controlled AV-interval which is shorter than said incipient fusion AV-interval, characterized in that said evoked response detector (4) includes an averaging means (16) provided to form an average amplitude value of said evoked response signal during a predetermined time window of each cardiac cycle, and a comparison means (12) arranged to compare said average value for each cardiac cycle with predetermined limit criteria and supply the result of said comparison to said determining means (13) for determining whether a detected evoked response signal results from an incipient fusion beat or a completely stimulated capture.

2. The heart stimulator according to claim 1, characterized in that said comparison means (12) is adapted to compare said average value with a predetermined limit value.

3. The heart stimulator according to claim 1, characterized in that said averaging means (16) is adapted to form a running average value of said evoked response signals during said predetermined time window from a predetermined number of the latest cardiac cycles which running average value is used in determining said limit criteria.

4. The heart stimulator according to claim 3, characterized in that said comparison means (12) is adapted to receive said running average value and compare the average value obtained during said time window of each cardiac cycle

with said running average value from immediately preceding cardiac cycles.

5. The heart stimulator according to claim 3, characterized in that said comparison means (12) is adapted to compare the variation of said average values obtained during said time window of the cardiac cycles with a predetermined variability limit.

6. The heart stimulator according to any of the preceding claims, characterized in that said controlling means (15) are adapted to modulate the AV-interval with a predetermined amount, and in that said comparison means (12) is adapted to then compare the variation of said average values obtained during said time window of the cardiac cycles with a predetermined variability limit.

7. The heart stimulator according to any of the claims 1 - 4, characterized in that said controlling means (15) are adapted to regularly prolong the AV-interval with a predetermined amount, and in that said comparison means (12) is adapted to then compare the said average amplitude values obtained during said time window of the cardiac cycles with said predetermined limit value and/or predetermined variability limit.

8. The heart stimulator according to claims 5 or 6, characterized in that said controlling means (15) are adapted to modulate the AV-interval with a predetermined amount, and in that said comparison means (12) is adapted to then compare the variation of said average values obtained during said time window of the cardiac cycles with said predetermined variability limit.

9. The heart stimulator according to any of the preceding claims, characterized in that said evoked response detector (4) is adapted to sample and digitize said evoked response signals for each heart beat in a predetermined evoked response time window starting a predetermined time after the delivery of a stimulation pulse to the ventricle to form the average value of said amplitude samples.

10. The heart stimulator according to claim 9, characterized in that sampling frequency and length of said evoked response time window are chosen such that a number of samples of the order of 20 is obtained within each evoked response time window.

11. The heart stimulator according to claim 9 or 10, characterized in that said evoked response detector (4) is adapted to determine the DC level of the measured ventricular signals and subtract this DC level from each sample before the average value is formed.

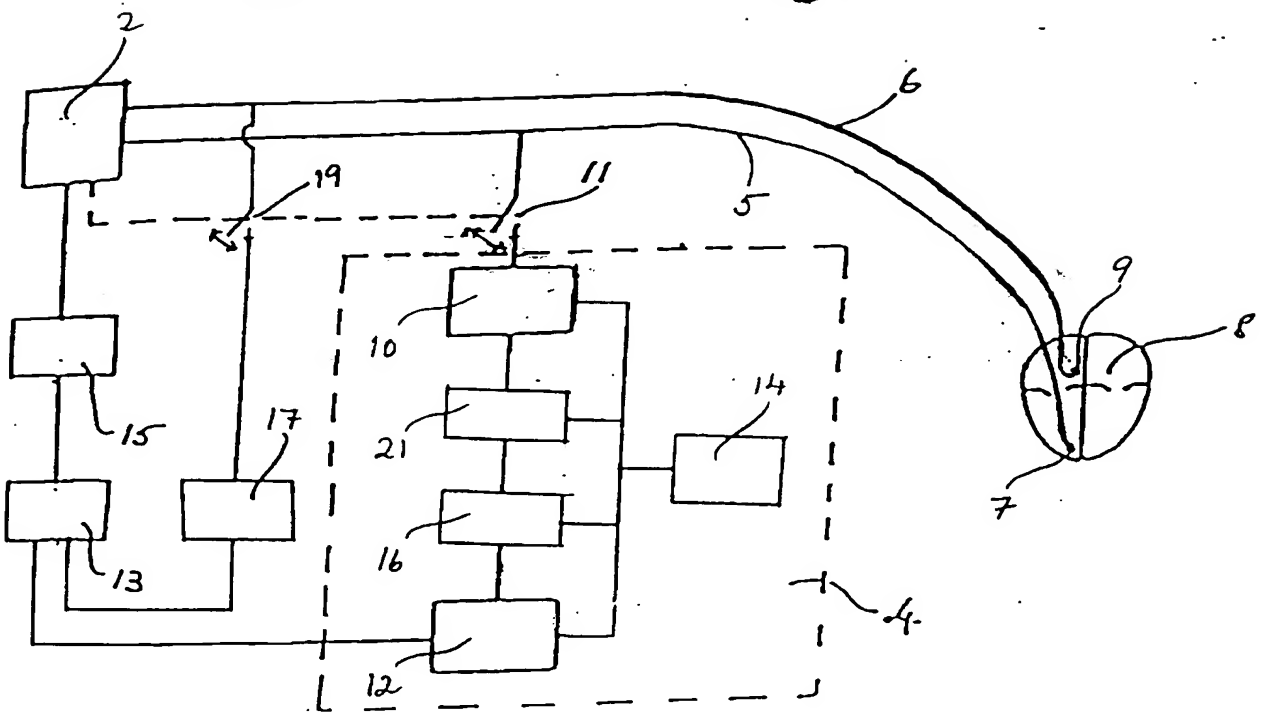
12. The heart stimulator according to any of the preceding claims, characterized in that a respiration signal determining means (28) is provided for determining a respiration signal, representing the respiration rate of the patient, from a predetermined number of said average values.

13. The heart stimulator according to claim 12, characterized in that said respiration signal determining means (28) is adapted to determine said respiration signal from variations of the amplitudes of said predetermined number of average values.

Abstract

A heart stimulator comprises atrial and ventricular stimulating means including a pulse generator (2) for producing stimulation pulses for delivery to the ventricle of a patient's heart (8). Atrial sensing means (7,9,17) are provided for sensing atrial signals and an evoked response detector (4) is provided for detecting the occurrence of incipient fusion beats from measured ventricular signals. Determining means (13) are provided for determining a incipient fusion AV-interval from the sensed atrial signals and detected fusion beats, and controlling means (15) are provided for controlling said pulse generator to deliver stimulation pulses at a controlled AV-interval which is shorter than the incipient fusion AV-interval. The evoked response detector (4) includes an averaging means (16) provided to form an average amplitude value of the measured ventricular signals during a predetermined time window of each cardiac cycle, and a comparison means (12) arranged to compare said average value for each cardiac cycle with predetermined limit criteria and supply the result of said comparison to said determining means (13) for determining whether a measured ventricular signal results from an incipient fusion beat or a completely stimulated capture.

(Fig. 1)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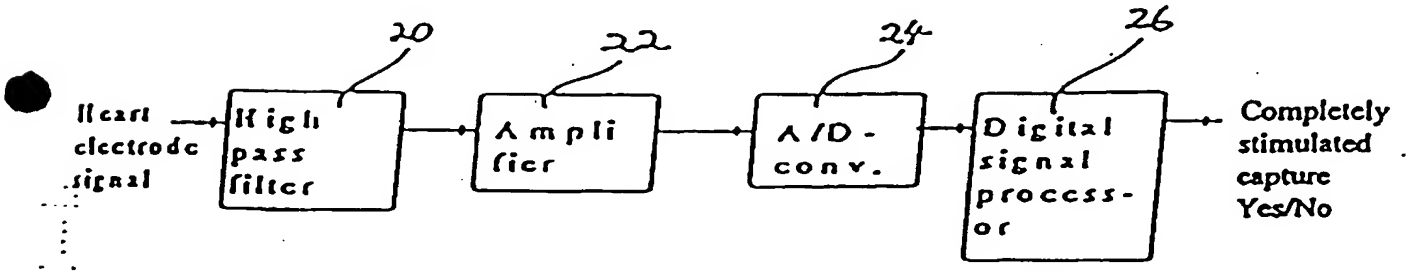
12

Fig. 1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26
Heart electrode signal
High pass filter
Amplifier
A/D-conv.
Digital signal processor
Completely stimulated capture Yes/No

Fig. 2

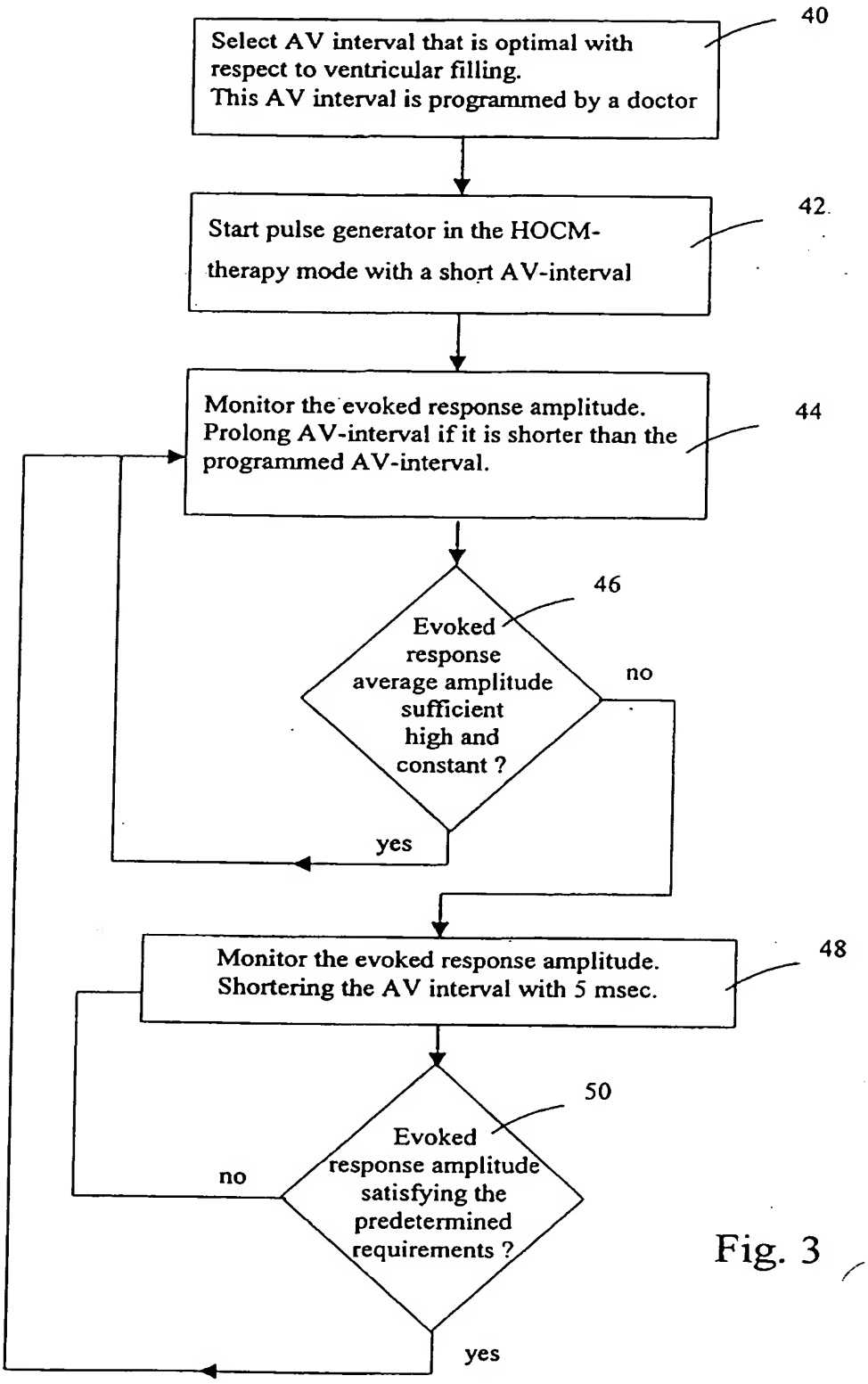

Fig. 3

Fig. 4